EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ellen Winner on 2/19/10. An initial telephonic interview was conducted with Ellen Winner on 2/2/09 (see attached interview summary) in which possible examiners amendments were discussed. At that time Ellen Winner stated that she would check with the applicant. On 2/19/10 applicants representative verified that the proposed amendments were acceptable.

The application has been amended as follows:

Claims 3-4 have been cancelled.

Claim 1,2,5,6,7,8 have been amended as follows:

1. A method for inducing melanogenesis in a human subject having a melanocortin 1 receptor[[s]] (MC1R) variant allele associated with loss of or diminished receptor function, which comprises the steps of:

i) identifying the MC1R variant using primer sequences selected from 5'-tggacaggactatggctgtg-3' (MC1R-1F - SEQ ID NO:1), 5'-tcttcagcacgctcttcat-3' (MC1R-1R - SEQ ID NO:2), 5'-

cttctacgcactgcgctacc-3' (MC1R-2F - SEQ ID NO: 3) and 5'-gctttaagtgtgctgggcag-3' (MC1R-2R - SEQ ID NO: 4), and

ii) administering to said subject an amount of [Nle^4, DPhe^7]-α-melanocyte stimulating hormone ([Nle^4, DPhe^7]-α-MSH) effective to induce melanogenesis by the melanocytes in the skin or other epidermal tissue of the subject, ~~wherein the MC1R variant is identified using primer sequences selected from 5'-tggacaggactatggctgtg-3' (MC1R-1F- SEQ ID NO:1), 5'-tctteagcacgctetteat-3' (MC1R-1R- SEQ ID NO:2), 5'-cttctacgcactgcgctacc-3' (MC1R-2F - SEQ ID NO: 3) and 5'-gctttaagtgtgctgggcag-3' (MC1R-2R- SEQ ID NO: 4).~~

2. The method of claim 1, wherein an admixture of said [Nle^4, DPhe^7]-α-MSH ~~analogue~~ with a further α-MSH analogue is administered in an amount effective to induce said melanogenesis, wherein said further α-MSH analogue is selected from:

(a) compounds of the formula:

Ac-Ser-Tyr-Ser-M-Gln-His-D-Phe-Arg-Trp-Gly-Lys-Pro-Val-NH_2

wherein M is Met, Nle or Lys; and

(b) compounds of the formula:

R_1-W-X-Y-Z-R_2

wherein

R_1 is Ac-Gly-, Ac-Met-Glu, Ac-Nle-Glu-, or Ac-Tyr-Glu-;

W is -His- or -D-His-;

X is -Phe-, -D-Phe-, -Tyr-, -D-Tyr-, or -(pNO_2)D-Phe^7-;

Y is -Arg- or -D-Arg-;

Z is -Trp- or-D-Trp-; and

R_2 is $-NH_2$; -Gly-NH_2; or -Gly-Lys-NH_2.

5. The method of claim 1, wherein an admixture of said [Nle^4, $DPhe^7$]-α-MSH with a further α-MSH analogue is administered in an amount effective to induce said melanogenesis, wherein the further α-MSH analogue is selected from the group consisting of:

Ac-Ser-Tyr-Ser-Nle-Glu-His-D-Phe-Arg-Trp-Lys-Gly-Pro-Val-NH_2,

Ac-Ser-Tyr-Ser-Nle-Asp-His-D-Phe-Arg-Trp-Lys-Gly-Pro-Val-NH_2,

Ac-Nle-Glu-His-D-Phe-Arg-Trp-Lys-Gly-Pro-Val-NH_2,

Ac-Nle-Asp-His- D-Phe-Arg-Trp-Lys-Gly-Pro-Val-NH_2,

Ac-Nle-Asp-His-D-Phe-Arg-Trp-Gly-NH_2,

Ac-Nle-Glu-His-D-Phe-Arg-Trp-Lys-NH_2,

Ac-Nle-Asp-His-D-Phe-Arg-Trp-Lys-NH_2,

Ac-Nle-Glu-His-D-Phe-Arg-Trp-Orn-NH_2,

Ac-Nle-Asp-His-D-Phe-Arg-Trp-Orn-NH_2,

Ac-Nle-Glu-His-D-Phe-Arg-Trp-Dab-NH_2,

Ac-Nle-Asp-His-D-Phe-Arg-Trp-Dab-NH_2,

Ac-Nle-Glu-His-D-Phe-Arg-Trp-Dpr-NH_2,

Ac-Nle-Glu-His-Phe-Arg-Trp-Lys-NH_2 (SEQ ID NO:5), and

Ac-Nle-Asp-His-Phe-Arg-Trp-Lys-NH_2 (SEQ ID NO:6).

6. The method of claim 1, wherein an admixture of said [Nle^4, $DPhe^7$]-α-MSH with a further α-MSH analogue is administered in an amount effective to induce said melanogenesis wherein the further α-MSH analogue is selected from the group consisting of:


Ac-Nle-Glu-His-D-Phe-Arg-Trp-Lys-Gly-Pro-Val-NH2 ,
Ac-Nle-Glu-His-D-Phe-Arg-Trp-Lys-NH2 ,
Ac-Nle-Asp-His-D-Phe-Arg-Trp-Lys-NH2 ,
Ac-Nle-Asp-His-D-Phe-Arg-Trp-Orn-NH2 ,
Ac-Nle-Asp-His-D-Phe-Arg-Trp-Dab-NH2 ,
Ac-Nle-Asp-His-D-Phe-Arg-Trp-Dpr-NH2 ,
Ac-Ser-Tyr-Ser-Nle-Asp-His-D-Phe-Arg-Trp-Lys-Gly-Pro-Val-NH2 ,
Ac-Ser-Try-Ser-Nle-Asp-His-D-Phe-Arg-Trp-Lys-NH2 ,
Ac-Tyr-Ser-Nle-Asp-His-D-Phe-Arg-Trp-Lys-NH2 ,
Ac-Ser-Nle-Asp-His-D-Phe-Arg-Trp-Lys-NH2 ,
Ac-Nle-Asp-His-D-Phe-Arg-Trp-Lys-NH2 ,
Ac-Nle-Asp-His-D-Phe-Arg-Trp-Lys-Gly-NH2 ,
Ac-Nle-Asp-His-D-Phe-Arg-Trp-Lys-Gly-Pro-NH2 ,
Ac-Nle-Asp-His-D-Phe-Arg-Trp-Lys-Gly-Pro-Val-NH2 ,and
Ac-Ser-Nle-Asp-His-D-Phe-Arg-Trp-Lys-Gly-Pro-Val-NH2 .

7. The method of claim 1, wherein an admixture of said [Nle^4, DPhe^7]-α-MSH with a further α-MSH analogue is administered in an amount effective to induce said melanogenesis wherein the further α-MSH analogue is:

[D-Phe^7]-α-MSH,
[Nle^4, D-Phe^7]-α-MSH,
[D-Ser^1, D-Phe^7]-α-MSH,
[D-Tyr^2, D-Phe^7]-α-MSH,
[D-Ser^3, D-Phe^7]-α-MSH,
[D-Met^4, D-Phe^7]-α-MSH,
[D-Glu^5, D-Phe^7]-α-MSH,

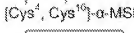
[D-His^6, D-Phe^7]-α-MSH,
[D-Phe^7, D-Arg^8]-α-MSH,
[D-Phe^7, D-Trp^9]-α-MSH,
[D-Phe^7, D-Lys^{11}]-α-MSH,
[D-Phe^7, D-Pro^{12}]-α-MSH,
[D-Phe^7, D-Val^{13}]-α-MSH,
[D-Ser^1, Nle^4, D-Phe^7]-α-MSH,
[D-Tyr^2, Nle^4, D-Phe^7]-α-MSH,
[D-Ser^3, Nle^4, D-Phe^7]-α-MSH,
[Nle^4, D-Glu^5, D-Phe^7]-α-MSH,
[Nle^4, D-His^8, D-Phe^7]-α-MSH,
[Nle^4, D-Phe^7, D-Arg^8]-α-MSH,
[Nle^4, D-Phe^7, D-Trp^9]-α-MSH,

[Nle^4, D-Phe^7, D-Lys^{11}]- α-MSH,

[Nle^4, D-Phe^7, D-Pro^{12}]-α-MSH,

[Nle^4, D-Phe^7, D-Val^{13}]-α-MSH,

[Cys^4, Cys^{10}]-α-MSH ,



[Cys^4, D-Phe^7, Cys^{10}]-α-MSH ,

[Cys^4, Cys^{11}]-α-MSH ,

[Cys^5, Cys^{10}]-α-MSH ,

[Cys^5, Cys^{11}]-α-MSH ,

[Cys^4, Cys^{10}]-α-MSH$_{4-13}$,

[Cys^4, Cys^{10}]-α-MSH$_{4-12}$,
[Nle^4, D-Phe^7]-α-MSH$_{4-10}$,
[Nle^4, D-Phe^7]-α-MSH$_{4-11}$,
[D-Phe^7]-α-MSH$_{5-11}$,
[Nle^4, D-Tyr^7]-α-MSH$_{4-11}$,
[(pNO$_2$)D-Phe^7]-α-MSH$_{4-11}$,
[Tyr^4, D-Phe^7]-α-MSH$_{4-10}$,
[Tyr^4, D-Phe^7]-α-MSH$_{4-11}$,
[Nle^4]-α-MSH$_{4-13}$,
[Nle^4, (pNO$_2$)D-Phe^7]-α-MSH$_{4-11}$,
[Nle^4, D-His^6]-α-MSH$_{4-11}$,
[Nle^4, D-His^5, D-Phe^7]-α-MSH$_{4-11}$,
[Nle^4, D-Arg^8]-α-MSH$_{4-11}$,
[Nle^4, D-Trp^8]-α-MSH$_{4-11}$,
[Nle^4, D-Phe^7, D-Trp^8]-α-MSH$_{4-11}$,
[Nle^4, D-Phe^7]-α-MSH$_{4-9}$, or
[Nle^4, D-Phe^7, D-Trp^8]-α-MSH$_{4-9}$.

8. The method of claim 1, wherein an admixture of said [Nle^4, DPhe^7]-α-MSH with a further α-MSH analogue is administered in an amount effective to induce said melanogenesis wherein the further α-MSH analogue is:

[Nle^4, D-Phe^7]-α- MSH$_{4-10}$,
[Nle^4, D-Phe^7]-α-MSH$_{4-11}$,
[Nle^4, D-Phe^7], D-Trp^8]-α-MSH$_{4-11}$, or
[Nle^4, D-Phe^7]-α-MSH$_{4-9}$.

As such, claims 1-2,5-8,12-14 (renumbered as claims 1-9 in the order presented) are allowable.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD T. NIEBAUER whose telephone number is (571)270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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